

# EXHIBIT 29

**Via Electronic Submission**

Ronald A Traud, Esq  
Office of the General Counsel  
U.S. International Trade Commission  
500 E Street S.W.  
Washington DC, 20436

**Re: Inv. No. 337-TA-1276**

Dear Mr. Traud,

My name is Mitchell Goldstein, M.D. I am submitting this response to the Commission's solicitation of comments on public interest issues raised by the ALJ's recommendations for relief in Investigation No. 337-TA-1276. In my view, the recommended relief is in the public interest, given the strong public interest in incentivizing investment into innovations that protect life-changing and life-saving technologies, such as those developed by Masimo. In contrast, the use of devices such as the Blood Oxygen feature that has been included in Apple Watches since the release of the Series 6, which does not include medical-grade technology for continuous measurement of oxygen saturation levels, damages public health and welfare. This is because consumers and even physicians commonly, but incorrectly, assume that pulse oximeters are all the same and that this feature is, therefore, capable of generating blood oxygen measurements for medical use.

I am a neonatologist in Southern California. I am affiliated with a number of hospitals, including Loma Linda University Medical Center in Loma Linda, CA, and Queens of the Valley Hospital in West Covina, CA. I am also a professor of Pediatrics in the Neonatology Division at Loma Linda University. Since 2018, I have been the Editor-in-Chief of Neonatology Today, the only peer-reviewed monthly newsletter available free to neonatologists, perinatologists, neonatal nurses, neonatal respiratory care specialists, parents, and anyone interested in the neonatal-perinatal space. I have written extensively on neonatology issues, including those related to the use of pulse oximetry. I obtained my medical degree from the University of Miami, completed my residency at the University of California Los Angeles, and held a fellowship at the University of California Irvine.

Patient care and consumer health are both dependent on the availability of equipment designed specifically to meet clinical accuracy. In my experience, Masimo is a true innovator in the field of medical devices, such as non-invasive physiological monitoring has significantly contributed to the public welfare by providing its cutting-edge technology to the public. I was first referred to Masimo in the early 1990s after coming to understand that other pulse oximeters, even

sold to hospitals, did not properly work on neonates.<sup>1</sup> This was a significant concern for neonatologists because of the risk of severe retinopathy of prematurity (ROP) in preterm newborns caused by high oxygen levels during the first few weeks after birth and low oxygen levels at later postmenstrual ages.<sup>2</sup> ROP is the second leading cause of blindness in childhood in the United States, and it has been known for over 50 years that excessive oxygen in the first few weeks of postnatal life is a major risk factor for ROP.<sup>3</sup> Accurate measurement of oxygen in premature infants also impacts treatment decisions for many other conditions.

During my training and early practice as a neonatologist, pulse oximeters (devices designed to measure the amount of oxygen in the blood) had been more than a casual annoyance. The incessant beeping and alarming of the non-functional devices were more of a distraction than a useful clinical tool. During one outbreak of retinopathy of prematurity (eye damage including blindness caused by too much oxygen given to premature infants), an associate of mine went through the neonatal intensive care unit, shutting off every oximeter in the room. These poorly performing pulse oximeters were the cause of inappropriate oxygen administration. Several weeks later, I was discussing our frustration with a manufacturer of newborn hospital equipment and expressed my concern that no one in the field was working to enhance the state of the art. He gave me the contact numbers for Masimo. This was the beginning of my interest in their technology.

Since 1994, I have been involved in clinical studies with Masimo Signal Extraction Technology (SET) pulse oximeters. My early studies demonstrated the practicality of a “Novel Pulse Oximeter Technology Resistant to Noise Artifact and Low Perfusion” and that this technology was “...Capable of Reliable Bradycardia (low heart rate) Monitoring in the Neonate”. Subsequently, I demonstrated a 90% reduction in false alarms in neonatal patients using Masimo technology. I showed that “Conventional Pulse Oximetry Can Give Spurious Data in a Neonatal Population at Risk for Retinopathy of Prematurity (ROP)” demonstrated the feasibility of reliable pulse oximetry operation during neonatal transport and revealed that Masimo SET reliably tracks neonatal heart rate variability. We investigated and concluded that “Selective Inattention to Pulse Oximetry Alarms is Unsafe in Infants at Risk for Apnea of Prematurity.” In studying Nellcor alarm management technology, SatSeconds™, we showed that in an effort to limit “nuisance” alarms, the Nellcor N-395 misses relevant desaturations and jeopardizes the detection of the infant at risk for sudden infant death syndrome.

Masimo’s technology led to a significant reduction in errors in calculating the blood oxygen levels in neonates, saving countless individuals from a lifetime of eye damage and even blindness. In fact, the success of Masimo’s SET Technology has been shown in clinical studies

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<sup>1</sup> A more detailed accounting of my experience with Masimo technology is available from my prior testimony before the Senate Judiciary Committee.

[https://www.judiciary.senate.gov/imo/media/doc/goldstein\\_testimony\\_04\\_30\\_02.pdf](https://www.judiciary.senate.gov/imo/media/doc/goldstein_testimony_04_30_02.pdf)

<sup>2</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4016714/>

<sup>3</sup> Id.

showing a strong positive association between the use of pulse oximetry with SET and a reduction in the incidence of ROP.<sup>4</sup>

Masimo's commitment to serving the neonate population via its innovative technology is essential to positive outcomes, and even the other hospital-focused pulse oximetry companies were not innovating to solve the problems we were experiencing with pulse oximetry. Masimo's commitment to innovation for the neonatal population is even more impressive given the relatively low population of neonate patients compared to adult patients and, therefore, the lack of a substantial commercial reason to commit resources to this specific population. For years I had to make do with inaccurate pulse oximeters made for adults in our neonate populations, leading to ROP issues. Masimo changed this by providing innovative technology and products made especially for this incredibly vulnerable population. It is essential to the health and welfare of all Americans that we continue to incentivize innovation through a strong intellectual property system and discourage infringement. In my opinion, without such protections, companies such as Masimo will lose financial incentives for assisting underserved patient populations with innovative technologies.

In contrast to Masimo's cutting-edge technology, the oxygen saturation measurement feature found in the Apple Watch does little, if anything, to aid the health and welfare of the public.<sup>5</sup> Apple recognizes that its blood oxygen measurements are "not intended for medical use and are only designed for general fitness and wellness purposes."<sup>6</sup> But, pulse oximetry is an important medical measurement, sometimes considered the "fifth vital sign." Apple does not show in its commercial advertising—except in the small print—that its pulse oximetry feature is not medically useful. I have met physicians who believe the Apple Watch must contain medical-grade pulse oximetry technology simply because it is sold by Apple and advertised as a beneficial health feature. Yet numerous commentators have written about the inaccuracy of the Apple Watch's measurements<sup>7</sup>. The inaccurate perception that Apple's pulse oximetry feature includes reliably accurate technology could potentially lead to both false positives and false negatives, hurting the public welfare.

### **The Recommended Remedies Support Healthcare Innovation**

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<sup>4</sup> <https://onlinelibrary.wiley.com/doi/full/10.1111/j.1651-2227.2010.02001.x>

<sup>5</sup> Because the pulse oximetry feature of the Apple Watch is only for those over the age of 18 it certainly has no benefit for the underserved neonate population who benefit from Masimo's innovation.

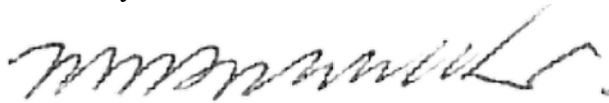
<sup>6</sup> <https://support.apple.com/en-us/HT211027>

<sup>7</sup> <https://www.washingtonpost.com/technology/2020/09/23/apple-watch-oximeter/> (article entitled "The new Apple Watch says my lungs may be sick. Or perfect. It can't decide."); <https://www.medpagetoday.com/opinion/skeptical-cardiologist/88729> ("If you are primarily excited by the oxygen sensing capabilities of [Apple Watch Series 6] I would recommend instead purchasing a \$20 finger tip pulse oximeter.")

Providing companies with appropriate relief at the ITC is an essential tool to protect American innovation. If the Commission confirms a Section 337 violation, an exclusion order and cease-and-desist order preventing Apple from importing and distributing products that rely on Masimo's innovation are the appropriate remedies. A conclusion otherwise would encourage infringement by Apple and others and would disincentivize innovation. This will have a dramatic impact on smaller companies that do not have the resources to compete unless they can protect their innovations.

I firmly believe the public's interest in encouraging investment in health technology innovation outweighs any potential public interest in Apple's continued infringement of valid intellectual property rights.

Sincerely Yours,

A handwritten signature in black ink, appearing to read 'mgoldstein', written in a cursive style.

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